**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| CAROL LEWIS,<br><br>Plaintiff,<br><br>v.<br><br>THOMAS E. PRICE<br>Acting Secretary, United States Department of Health and Human Services,<br><br>Defendant. | ) | Civil Action No.:<br>1:15-CV-13530-NMG |

**MEMORANDUM OF LAW IN SUPPORT OF HHS' MOTION TO AFFIRM HHS' DECISION AND IN OPPOSITION TO PLAINTIFF'SMOTION FOR SUMMARY JUDGMENT**

Defendant Thomas E. Price, Secretary of Health and Human Services ("the Acting Secretary" or "Defendant"), requests that the Court affirm the decision of the Medicare Appeals Council denying coverage for Plaintiff's continuous glucose monitoring system and deny Plaintiff's Motion for Summary Judgment, for the reasons set forth below.

## I. INTRODUCTION

Plaintiff, Carol Lewis, filed this action pursuant to the Medicare statute (42 U.S.C. § 1395 *et seq*.) to seek judicial review of the final decision of the Secretary denying Medicare Part B coverage for disposable sensors and an external transmitter for use with her continuous glucose monitoring system (collectively "CGM").[1] The Secretary, through the Medicare

[1] CGMs consist of three components: a disposable sensor, a transmitter, and a receiver. AR 441. The disposable sensor is positioned subcutaneously under the skin and measures the interstitial glucose levels, the sensor sends the interstitial glucose measurement to the transmitter, and the transmitter relays the measurement to a receiver where Plaintiff may view it. Admin. R. ("AR") 159, 190. For purposes of this Memorandum, the term CGM will refer to the CGM that Plaintiff requested coverage for and not the "closed loop" (*see infra* IV.B at 14) or the "therapeutic" CGM systems (*see infra* II.A.2 at 7).

Appeals Council ("the Appeals Council"), determined that the disposable sensors and external transmitter were not covered because Plaintiff's CGM did not meet the definition of durable medical equipment ("DME") and thus did not fall within a defined Medicare benefit category that would permit coverage. AR 3-13. The Secretary requests that the Court affirm his final decision and deny Plaintiff's Motion for Summary Judgment because the Appeals Court decision is supported by substantial evidence in the record and comports with the Medicare statute, regulations, and applicable policies. *See* 42 U.S.C. §§ 405(g), 1395ff.

## II. STATUTORY AND REGULATORY FRAMEWORK

### A. Medicare Statute

The Medicare statute (Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*.) establishes a federal health insurance program for the aged, the disabled, and persons suffering from end stage renal disease. Original "fee-for-service" Medicare consists of two basic parts. Part A of Medicare, 42 U.S.C. § 1395c *et seq.*, provides for the payment of inpatient hospital and related post-hospital benefits on behalf of eligible individuals. Part B of Medicare, 42 U.S.C. § 1395j *et seq.*, establishes a voluntary supplemental insurance program intended for the payment of certain other health services. *See* 42 U.S.C. § 1395k.

In enacting the Medicare program, Congress provided substantial authority to the Secretary (who acts through the Centers for Medicare & Medicaid Services ("CMS") in administering the program) to prescribe regulations necessary to implement and effectuate the Medicare statute. 42 U.S.C. § 1395hh(a)(1). The Medicare statute permits the Secretary to contract with private entities, known as Medicare Administrative Contractors ("MACs"), to assist in administering the Medicare program. 42 U.S.C. § 1395kk-1. The MACs are

responsible for processing payments, developing local coverage determinations, and providing assorted services to providers and beneficiaries. 42 U.S.C. § 1395kk-1.

**1. Medicare Coverage**

For items and services to be covered by Medicare, they must be (1) eligible for coverage under a defined benefit category, (2) reasonable and necessary for the diagnosis or treatment of an injury or illness, and (3) not otherwise excluded. 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A),(B); *see also*, *Anghel v. Sebelius*, 912 F.Supp.2d 4, 10 (E.D.N.Y. 2012).

The Medicare statute provides coverage for "medical and other health services," which is defined to include durable medical equipment ("DME"). 42 U.S.C. § 1395x(s), (s)(6). The Medicare statute defines DME as follows:

> The term 'durable medical equipment' includes iron lungs, oxygen tents, hospital beds, and wheelchairs . . . used in the patient's home . . . [,] whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories . . . .

42 U.S.C. § 1395x(n).

CMS regulations establish the criteria for DME. *See Medicare Program; Final Rule on Durable Medical Equipment*, 76 Fed. Reg. 70,228, 70,286 (Nov. 10, 2011) (discussing the history of the DME benefit and regulatory criteria for DME). Pursuant to these regulations, DME is specifically defined as

> . . . [E]quipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.
(4) Generally is not useful to an individual in the absence of an illness or injury.
(5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

CMS has set forth interpretative guidance for these regulations in its *Medicare Benefit Policy Manual* ("MBPM"), CMS Pub. 100-02, Chapter ("Ch.") 15, § 110 (effective Apr. 1, 2013), http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html. The MBPM, in discussing equipment that is primarily and customarily used to serve a medical purpose," states that "first-aid or precautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature" and, therefore, "are not considered covered DME." *Id.* at § 110.1-B-2. As noted, the statutory requirements for Medicare coverage include the requirement that an item or service be reasonable and necessary for the diagnosis and treatment of an injury or illness. With regard to whether DME is reasonable and necessary in a particular case, the MPBM explains that payment will be barred "for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case . . . ." *Id.* at § 110.1-C

In addition to the Medicare statute, regulations, and the MBPM guidance related to determining whether an item or service qualifies for Medicare coverage, the statute authorizes the Secretary to issue binding National Coverage Determinations ("NCDs"). *See* 42 U.S.C. § 1395y(l). The statute defines an NCD as "a determination by the Secretary with respect to whether a particular item or service is covered nationally under [the Medicare program]." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1062(a). *See also Medicare Program; National Coverage Decisions*, 54 Fed. Reg. 34,555 (Aug. 21, 1989). In issuing an NCD, the Secretary draws on the expertise of various components of HHS, as well as sectors of the medical and

scientific community and other interested parties. *See Medicare Program; Revised Process for Making Medicare National Coverage Determinations*, 68 Fed. Reg. 55,634 (Sept. 26, 2003). An NCD is binding on the MACs that process claims, on Administrative Law Judges ("ALJs") reviewing beneficiary claims, and on the Appeals Council. 42 C.F.R. § 405.1060(a)(4).

The Medicare statute also authorizes MACs to issue Local Coverage Determinations ("LCDs") that identify circumstances in which particular items or services will or will not be covered within the jurisdiction of the particular MAC. 42 U.S.C. § 1395ff(f)(2)(B). LCDs "specify under what clinical circumstances a service is considered to be reasonable and necessary," and are developed after "consider[ation of] medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community." *Medicare Program Integrity Manual* ("MPIM"), CMS Pub. No. 100-08, Ch. 13, § 13.1.3 (effective Jan. 1, 2012), http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. LCDs are not binding on ALJs or the Council but should be given substantial deference if applicable to a particular case. 42 C.F.R. § 405.1062. MACs may also issue guidance in the form of Local Coverage Articles ("LCAs"), which may address benefit category determinations, coding guidelines, or statutory exclusion provisions pertinent to particular items or services discussed in a related LCD.[2] *See* MPIM, Ch. 13, § 13.1.3; Local Coverage Determination, CMS.GOV,

[2] The "reasonable and necessary" language now contained in LCDs was formerly included in Local Medical Review Policies ("LMRPs"). 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). LMRPs were broader in scope than LCDs, as they included both reasonable and necessary determinations in accordance with 42 U.S.C. § 1395y(a)(1)(A) as well as coding provisions, benefit category provisions, and/or statutory exclusion provisions. *See Id*. With the passage of Section 522 of the Benefits Improvement and Protection Act ("BIPA"), Pub. L. 106-554, LCDs were separately designated to contain only information regarding whether a particular item or service was covered on a contractor-wide basis in accordance with 42 U.S.C. § 1395y(a)(1)(A) (reasonable and necessary). *Id*. As a result of BIPA, CMS noted that it intended to work with contractors to divide LMRPs into separate LCD and non-LCD documents, *e.g.*, LCAs. *Id*.

www.cms.gov/medicare/coverage/determinationprocess/LCDs.html; *see also* 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003).

In the absence of an applicable NCD, a MAC is required to interpret and apply the "reasonable and necessary" limitation of 42 U.S.C. § 1395y(a)(1)(A) when it determines whether Medicare should cover a claim. *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004). "The Secretary requires Medicare contractors to use LCDs to aid in this determination—specifically, when the contractor identifies an item or service that is never covered in certain circumstances and wishes to establish automated review or when widespread, significant risk to Medicare funds dictates." *Id.* (citing the MPLM). *See also Heckler v. Ringer*, 466 U.S. 602, 617 (1984) ("The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions."). Furthermore, the item or service must satisfy the other coverage requirements, including that it is eligible for coverage under a defined Medicare benefit category.

**2. Medicare Coverage of CGMs**

Plaintiff''s CGM is functionally different from a home blood glucose monitor. Plaintiff's CGM consists of a disposable sensor, a transmitter, and a receiver, and it acts to continuously measure Plaintiff's interstitial fluid glucose levels, that is, glucose levels in the fluid surrounding the cells of the tissue beneath the skin. Based on the readings, the CGM alerts Plaintiff of when to take a home blood glucose reading – that is, a fingerstick reading -- to determine if it is necessary to make adjustments to her course of therapy. AR 10-11, 159, 190, 881-888. In contrast to the CGM, a home blood glucose monitor measures the glucose level in Plaintiff's blood directly, through use of a disposable sterile lancet that draws a drop of blood; the blood is

placed on a reagent strip and inserted into the glucose monitor to obtain a blood glucose reading. AR 640-641; *National Coverage Determination 40.2: Home Blood Glucose Monitors*, CMS Pub. No. 100-3 (eff. June 19, 2006); Medicare Coverage Database, CMS.GOV, www.cms.gov/medicare-coverage-database/indexes/ncd-by-chapter-and-section-index.aspx. Once the blood glucose reading is made, Plaintiff is able to use the result to make immediate therapeutic decisions, typically whether to increase or decrease insulin medication. *Id*.

The Medicare statute expressly covers home blood glucose monitors under the DME benefit if there is a reasonable and medically necessary need for the monitors. 42 U.S.C. § 1395x(n). The statute is silent on coverage of CGMs. *Id*. NCD 40.2 discusses coverage for home blood glucose monitors, but is silent on coverage of CGMs. *NCD 40.2,* CMS Pub. No. 100-3. As a result, it is necessary to turn to CMS regulations and guidance to determine whether Plaintiff's CGM may be covered as DME and, additionally, whether the device is reasonable and necessary.

CMS' regulations provide that in order for an item to fall within the DME benefit category, the item must be primarily and customarily used to serve a medical purpose. 42 C.F.R. § 414.202. An LCD -- LCD L11530/L33822 -- issued by NHIC, the MAC assigned to Plaintiff's jurisdiction, applies to home blood glucose monitors and does not discuss coverage of CGMs; it merely lists certain CGM coding information for contractor reference in its section on the Healthcare Common Procedure Coding System ("HCPCS"), and provides that "[t]he appearance of a code in this section does not necessarily indicate coverage." AR 642-643. However, in its related LCA - - LCA A33614/A52464 --, NHIC discusses information regarding benefit categories for certain blood glucose monitoring supplies and devices, and explains that "[c]ontinuous glucose monitors (A9276-A9278) are considered precautionary and therefore non-

covered under the DME benefit." AR 9; *see also* AR 11 (FDA labeling of Plaintiff's CGM indicates that it "is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required.")

Similarly, in CMS Ruling No. 1682, CMS concluded that Medicare Part B "does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." CMS Ruling No. 1682-R, at 6-7 (Jan. 12, 2017), https://www.cms.gov/Regulations-and-Guidance /Guidance/Rulings/Downloads/CMS1682R.pdf.[3] It explains "[i]n our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions." *Id*. at 7. The Ruling goes on to note that the FDA has recently approved expanding the indications of one CGM device that is technologically advanced to the point that it is able to replace blood glucose monitors for making diabetes treatment decisions. *Id*. CMS refers to CGMs that are approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions as "therapeutic CGMs" and such therapeutic CGMs fall within the Medicare Part B benefit category for DME, if they also meet the other statutory criteria for coverage, e.g., the reasonable and necessary criteria under 42 U.S.C. § 1395y(a)(1)(A). *Id*. at 11, 13-15. Plaintiff is not requesting coverage of a therapeutic CGM, and, this action is not related to a therapeutic CGM.

[3] CMS Ruling No. 1682 was not issued until January 12, 2017, after the dates of coverage in issue here. However, the Ruling is illuminating on CMS' overall policy scheme regarding CGMs and further explains NHIC's use of the term "precautionary" in LCA A33614/A52464.

**3. The Appeals Process**

As the statutory and regulatory framework establishes, a Medicare beneficiary who seeks to challenge a denial of coverage must initially request that the MAC reconsider. 42 U.S.C. § 13955ff(a)(3)(B)(i); 42 C.F.R. §§ 405.904(a)(2), 405.948. Thereafter, the beneficiary may request reconsideration by a qualified independent contractor ("QIC"). 42 U.S.C. §§ 1395ff(c)(1), (2); 42 C.F.R. § 405.960. After reconsideration, the beneficiary may request a hearing before an ALJ. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Last, the beneficiary may request an Appeals Council review (or, alternatively, the Appeals Council may elect on its own motion to review the ALJ's decision). 42 C.F.R. §§ 405.1100, 405.1110. The Appeals Council has the authority to adopt, modify, or reverse the ALJ's decision. 42 C.F.R. § 405.1128. The Appeals Council's decision is final and binding on all parties unless it reopens its decision in accordance with § 405.980 or a U.S. District Court issues a modifying decision. 42 C.F.R. § 405.1130. A party may file an action in U.S. District Court within 60 calendar days after receipt of the Appeals Council's decision or, if the Appeals Council fails to timely issue a decision, after the Appeals Council's applicable adjudication period expires. 42 C.F.R. §§ 405.1100, 405.1136.

**B. Standard of Review**

Under the Medicare statute, judicial review of an administrative decision regarding claims for benefits under the Medicare statute is to be based on the pleadings and the transcript of the administrative record. 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff. "The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g), 42 U.S.C. §§ 1395ff(b), 1395w-22(g)(5)). That is, the Court "'must uphold the

Secretary's findings . . . if a reasonable mind, reviewing the evidence in the record as a whole, could accept it as adequate to support his conclusion.'" *Irlanda Ortiz v. Sec'y of Health & Human Servs.*, 955 F.2d 765, 768 (1st Cir. 1991) (citing *Rodriguez v. Sec'y of Health & Human Servs.*, 647 F.2d 218, 222 (1st Cir. 1981); *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (explaining that substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion").

In reaching its decision, where the facts permit diverse inferences, the Court must afford the Secretary deference and affirm his decision, even if the Court might have reached a different result. *Weiler v. Shalala*, 922 F. Supp. 689, 694 (D. Mass. 1996) (citing *Lizotte v. Sec'y of Health & Human Servs.*, 654 F.2d 127, 128 (1st Cir. 1981). The Secretary's decision, if supported, must be upheld even if there is also substantial evidence supporting the plaintiff's position. *See, e.g., Schauer v. Schweiker*, 675 F.2d 55, 57 (2d Cir. 1982); *Rutherford v. Schweiker*, 685 F.2d 60, 62 (2d Cir. 1982); *Cutlip v. Sec'y of Health & Human Servs.*, 25 F.3d 284, 286 (6th Cir. 1994). Finally, the plaintiff bears the ultimate burden of proving entitlement to Medicare coverage. *Hoye v. Sebelius*, 778 F. Supp. 2d 145, 149 (D. Mass. 2011) (citing *Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995)).

## III. FACTUAL BACKGROUND

Plaintiff is a diabetic with Type I diabetes. AR 644-46. She is a Medicare Part B beneficiary who resides in Massachusetts. Pl.'s Compl. ¶ 17-18, AR 828-31. Pursuant to her physician's prescription, Plaintiff uses a Medtronic CGM provided by Minimed Distribution Corporation as well as a home blood glucose monitor. AR 828-31,881-888. According to the administrative record, Plaintiff's physician prescribed a CGM because Plaintiff experiences significant variability in glycemic control that puts her at risk for hypoglycemic reactions. AR

828. Plaintiff's physician opined that the particular CGM's ability to continuously monitor Plaintiff's glucose level has permitted Plaintiff to detect both hypo- and hyperglycemic reactions more quickly than she would be able to using only the home blood glucose monitor, resulting in fewer incidents of hypoglycemia and improved glucose management. AR 828-29.

Plaintiff's CGM consists of a disposable sensor, a transmitter, and a receiver. AR 441. The disposable sensor, which measures the interstitial glucose levels, is positioned subcutaneously under the skin and replaced every 3 to 7 days. AR 190. The interstitial glucose measurements are sent continuously from the sensor to a transmitter and then to a receiver where Plaintiff may view them. AR 190. However, the interstitial glucose measurements taken by Plaintiff's CGM are not accurate enough to use for therapeutic decisions, and, therefore, Plaintiff is required to retest her glucose measurement using the home blood glucose monitor before making any medication adjustments. AR 9-10, 881-888. For that reason, Plaintiff's CGM device is approved by the FDA for adjunctive use only and "is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick [traditional blood glucose monitor] may be required." AR 11.

Plaintiff requested Medicare Part B coverage of disposable sensors and an external transmitter for use with her Medtronic CGM, for the period of March 12, 2012 to September 17, 2012. AR 752-755. CMS issued Medicare Summary Notices informing Plaintiff that the sensors and the transmitter were not covered by Medicare. AR 764-68. Plaintiff appealed the coverage denials and received unfavorable redetermination and reconsideration decisions. AR 679-686, 752-755. Plaintiff then appealed the reconsideration decision to an Administrative Law Judge ("ALJ") at the Office of Medicare Hearings and Appeals ("OMHA"), who issued an unfavorable decision, and then to the Appeals Council that, while modifying the basis of the ALJ's decision,

ultimately affirmed the ALJ's conclusion that the CGM sensors and transmitter requested by Plaintiff were not covered under Medicare. AR 3-13, AR58-65. The Appeals Council decision held that Plaintiff's CGM did not qualify as DME and, thus, did not fall within a defined Medicare benefit category and were not covered by Medicare. AR 3-13. As a result, Plaintiff's CGM (including the requested components) was not eligible for Medicare coverage. *Id*. In reaching its decision, the Appeals Council relied on statutory and regulatory provisions as well as NCD 40.2, LCD 11530/L33822, and related LCA A33614/A52464 "since the CGM does not substitute for the existing means of controlling insulin usage, we conclude that it merely provides an added precaution and does not itself serve a primary medical purpose." AR 7-11.

## IV. ARGUMENT

The Secretary's final decision denying Plaintiff coverage for disposable sensors and transmitters for use with her CGM should be affirmed because it is supported by substantial evidence. In reaching this decision, the Court is required to review Plaintiff's claim under the Medicare statute, as opposed to the APA, and is required to defer to the Secretary's conclusion that CGMs do not qualify as DME and thus do not fall within a defined Medicare benefit category that is eligible for coverage.

### A. Plaintiff's Claims Must Be Reviewed Pursuant To The Standard Set Forth In The Medicare Statute

Plaintiff requests that this Court review the Acting Secretary's final decision under the arbitrary and capricious standard set forth in the APA; however, the APA neither provides for judicial review in this action, nor sets forth the correct standard of review.

Plaintiff's cause of action is predicated on her denial of coverage for benefits under Medicare Part B. Judicial review of a final decision by the Secretary of HHS pertaining to the denial of Medicare coverage is limited to the grant of jurisdiction provided by the Medicare

statute. *See* 42 U.S.C. § 405(g), *incorporated into Medicare statute at* 42 U.S.C. § 1395ff(b); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (holding that virtually all claims where both the standing and substantive basis of the claim is the Medicare Act must be channeled through the agency and decided in accordance with § 405(g)-(h)); *Puerto Rican Ass'n of Physical Med. & Rehab., Inc. v. U.S.*, 521 F.3d 46, 48 (1st Cir. 2008); *Beechwood Restorative Care Ctr. v. Thompson*, 494 F.Supp.2d 181, 191 (2d Cir. 2007). Indeed, as the Second Circuit has recognized, "in an action under § 405(g), a court should 'review the Secretary's actions pursuant to the specific provisions of § 405(g) where applicable.'" *Beechwood*, 494 F. Supp.2d at 193 (citing *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 77-78 (2d Cir. 2006)). It is only where a reviewing standard is absent that the judicial review provisions of the APA, which does not provide an independent grant of jurisdiction, may be applicable. *Id. See also Califano v. Sanders*, 430 U.S. 99, 104-107 (1977); *New York Pub. Interest Research Group, Inc. v. Johnson*, 427 F.3d 172, 179 (2d Cir. 2005). Here, given that 42 U.S.C. § 405(g) provides a clear standard of review for the dispute at issue, Plaintiff's claims are required to be reviewed pursuant to that statute.

**B. The Acting Secretary's Denial Of Coverage Is Supported By Substantial Evidence In The Record And Should Be Affirmed.**

The Secretary's final decision denying Medicare coverage for disposable sensors and a transmitter for Plaintiff's CGM is supported by substantial evidence and, therefore, should be affirmed. The Appeals Council properly recognized Plaintiff's CGM is a "precautionary" item, and, accordingly, does not meet Medicare coverage requirements.

While the record contains evidence that Plaintiff has benefitted from use of the CGM, not every item or service that may benefit patients is covered by Medicare. To be covered by Medicare, an item or service must fall within a defined benefit category, must be reasonable and

necessary for the diagnosis or treatment of an injury or illness, and must meet all applicable statutory and regulatory requirements. *See* 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A); 68 Fed. Reg. at 55,635 ("Medicare payment is contingent upon a determination that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is 'reasonably necessary.'"); *Anghel*, 912 F.Supp.2d at 4. Here, substantial evidence in the record demonstrates that the type of CGM utilized by Plaintiff is not, as the Appeals Council determined, eligible for coverage under a defined benefit category. The Appeals Council's decision is consistent with CMS' established criteria for DME. Accordingly, the decision of the Secretary is consistent with the Medicare statute and is free from legal error.

As noted, the Medicare statute expressly permits coverage for "medical and other health services", which includes coverage for DME. 42 U.S.C. §§ 1395k, 1395x(s), 1395x(s)(6). DME is statutorily defined to permit coverage for home blood glucose monitors; however, the statute does not provide for coverage of CGMs, which are functionally different from blood glucose monitors. 42 U.S.C. § 1395x(n). CMS provides guidance on DME in its regulations and policy guidance, which provide that in order for equipment to be covered as DME, it must be able to withstand repeated use, have an effective life expectancy of at least three years, primarily and customarily serve a medical purpose, generally not be useful to an individual in the absence of an illness or injury, and be appropriate for use in the home. 42 C.F.R. § 414.202. In the CMS MBPM, CMS provides that precautionary equipment is considered nonmedical in nature and is, therefore, not covered as DME. MBPM, CMS Pub. 100-02, Ch. 15, § 110. And, NHIC, the appointed CMS MAC, concluded that CGMs are not covered because their function is merely precautionary. AR 9. Both the CMS' determination that precautionary equipment is not covered as DME and NHIC's determination that CGMs are not covered because they are precautionary is

based on the underlying conclusion that precautionary equipment is not primarily medical in nature.

In making its decision, the Appeals Council examined NHIC's determination that CGMs are precautionary. AR 11. The Appeals Council's agreement with the NHIC determination that Plaintiff's CGM is precautionary, and thus not covered, is supported by substantial evidence. AR 10-11. As detailed throughout the administrative record, Plaintiff's CGM is intended to alert her as to when to determine her blood glucose level by using her home blood glucose monitor and the CGM cannot be relied on independently to make therapeutic adjustments. *Id*. For this reason, the CGM's purpose is not primarily medical or therapeutic. AR 10-11 (the manufacturer of Plaintiff's CGM cautions that it must be used in conjunction with traditional finger stick testing), 888 (Plaintiff's physician noted that Plaintiff must consult home blood glucose monitor before adjusting pump doses); AR 11 (the FDA states that Plaintiff's CGM device "is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required"). It is the home blood glucose monitor that is used to make medical decisions, not the CGM.

Plaintiff asserts that relevant professional medical societies and experts in the care of diabetes have determined that CGMs are "medical devices," but this does not mean that CGMs is eligible for Medicare coverage as a DME. Plaintiff's argument omits the fact that these societies and experts provide the same limitations on the use of a CGM that the FDA and Plaintiff's physician do, namely that the device must be used **adjunctively** with a home blood glucose monitor and thus the devices do not **primarily** serve a medical purpose. AR 79-84 (the American Association of Clinical Endocrinologist, Continuous Glucose Monitoring Task Force noted that CGMs must be calibrated through self-monitoring of blood glucose, i.e. the finger

stick method, and that use of the finger stick method is required in order to make acute treatment decisions); AR 100 (a study published in the *Journal of Diabetes Technology & Therapeutics* directed its participants to "use CGM data as an adjunct to, and not as a replacement for [self-monitoring of blood glucose] fingersticks when making diabetes-related treatment decisions (e.g. insulin dose modifications)" and concluded that the accuracy of CGMs does not yet equal the accuracy of self-monitoring of blood glucose and thus CGMs are best used as an adjunctive device until technological advances are made).

Plaintiff's reliance on subsequent developments and/or statements by third parties—in particular, the FDA's recent approval of a "closed loop" CGM system, the opinion of Plaintiff's treating physician, and favorable ALJ decisions involving requests for CGM coverage— is unpersuasive because the materials do not demonstrate that Plaintiff's CGM may be used independently to adjust her therapy regimen.

Ab initio, Plaintiff's references to FDA's recent approval and subsequent ALJ decisions should not be considered when deciding this matter because these materials are not in the administrative record. 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff; *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 102 (D. Mass. 2009) ("Because this case arises under section 1395ff(b)(1)(A), the court's factual review is limited to the administrative record"), *citing Landers v. Leavitt*, 2006 WL 2560279, at 3 (D. Conn. 2006) (*citing Mathews v. Weber*, 423 U.S. 261, 263) (1976) ("holding that under 42 U.S.C. § 405(g), the 'court may consider only the pleadings and administrative record' and 'neither party may put any additional evidence before the district court[,];" *aff'd* 545 F.3d 98 (2d Cir. 2008)).

Even if these materials were in the record, they would fail to demonstrate that Medicare Part B coverage is appropriate. Plaintiff asserts that the FDA has recently approved a "'closed

loop' CGM/insulin pump system that directly informs the insulin pump when to administer insulin to control glucose levels." Pl.'s mem. at 16.[4] Plaintiff point highlights the fact that technological advances are needed (and, in fact, as CMS Ruling No. 1682 demonstrates that technological advances, have, in very limited instances, occurred) to permit CGMs to act as primarily medical devices by permitting its users to make adjustments to their therapy based solely on the CGM glucose readings. The record here is clear that, unlike a closed loop system, the device Plaintiff for which is requesting coverage for is unable to prepare the basis for the therapeutic decision.[5]

Next, Plaintiff requests that this Court adopt the opinion of her treating physician in order to conclude that Plaintiff is entitled to Medicare Part B coverage. Plaintiff's statement from her treating physician—indicating that the CGM is not precautionary but rather medically necessary for Plaintiff—does not undercut the Acting Secretary's denial of coverage because the physician's determination of the device's appropriateness for Plaintiff's condition is not binding on the determination of whether equipment is "medically necessary" so as to fit the criteria for Medicare coverage. *State of N.Y. on Behalf of Bodnar v. Sec'y of Health & Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990) ("The Medicare statute unambiguously vests final authority in the Secretary, and no one else, to determine whether a service is reasonable and necessary, and thus

[4] Plaintiff appears to argue that the FDA's approval of the "closed loop" system indicates that the "closed loop" CGM permits its users to make direct therapeutic decisions based on its measurements. However, to the contrary, the FDA's approval of the closed-loop CGM states, "[t]he CGM component of the [closed loop system] is not intended to be used directly for making manual insulin therapy adjustments, but rather to provide an indication of when a glucose measurement should be taken" and, based on the language in CMS Ruling No. 1682, CMS has declined to cover it. FDA Recently-Approved Devices, The 670G System–P160017, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm522764.htm.

[5] CMS only recognizes "therapeutic" CGMs that are approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions as DME. CMS Ruling No. 1682. The only FDA-approved CGM device that meets that requirement is the Dexcom G5 Mobile. *CMS Classify Therapeutic CGMs as Durable Medical Equipment Under Medicare Part B*, Dexcom, https://www.dexcom.com/news/dexcom-cgm-medicare (Jan. 13, 2017).

whether reimbursement should be made"); *see also Heckler v. Campbell*, 461 U.S. 458, 466 (1983) ("Congress has 'conferred on the Secretary exceptionally broad authority to prescribe standards for applying certain sections of the [Social Security] Act.'" (citation omitted)). Here, because Plaintiff cannot make therapeutic decisions based solely on the glucose readings produced by her CGM, the device does not perform a medically necessary function consistent with the Secretary's conditions for coverage. Accordingly, Plaintiff's treating physician's statement does not change or affect the coverage determination. *See* MBPM, Ch. 15, § 110.1-C (explaining that a beneficiary is not entitled to coverage for "equipment which cannot be reasonably expected to perform a therapeutic function . . . .").

Finally, Plaintiff's reliance on the ALJ's decision in the administrative case she filed challenging the validity of LCD L11530/L33822 and LCA A33614/A52464, as well as her reliance on subsequent ALJ decisions, is unwarranted. In Plaintiff's administrative challenge to the LCD, the Secretary has challenged the ALJ's decision; and, accordingly, the ALJ's decision in that case does not represent the final decision of the Secretary because the case remains pending with the Departmental Appeals Board ("DAB"). *See* 42 C.F.R. § 426.490. Moreover, that case involves a challenge made under different authority, 42 C.F.R. Part 426. Given that these cases present different issues and are grounded in different statutory and regulatory authorities, Plaintiff cannot argue that any decision in that ongoing litigation supports the notion that the Secretary acted unreasonably here, and, indeed, this Court is not required to defer to subsequent ALJ decisions in that proceeding.

In conclusion, because Plaintiff's CGM cannot be used to make therapeutic decisions, it does not primarily and customarily serve a medical purpose, and it is not covered as DME under Medicare Part B. Thus, the Appeals Council's decision denying Plaintiff's request for coverage

is consistent with the Medicare statute and regulations is supported by substantial evidence, and should be upheld.

### C. The Appeals Council Properly Relied on Applicable Medicare Guidance When Reaching Its Decision

As a final matter, Plaintiff asserts that the Appeals Council's decision should be set aside as contrary to law because the Appeals Council improperly relied on LCA A33614/A52464 when elevating it to LCD status. Pl's mem. at 17. However, Plaintiff's argument ignores the reasoning of the Appeals Council's decision.

Even though the Appeals Council is not required to follow "LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions," the Appeals Council is required to "give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). As noted, for items to be covered by Medicare, they must be (1) eligible for coverage under a defined benefit category, (2) reasonable and necessary for the diagnosis or treatment of an injury or illness, and (3) not otherwise excluded. 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A),(B). The Appeals Council determined that Plaintiff's CGM is not eligible for Medicare reimbursement because it is not a DME, that is, it is not a "defined benefit". The MBPM, in discussing equipment that is primarily and customarily used to serve a medical purpose," states that "first-aid or precautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature" and, therefore, "are not considered covered DME." *Id.* at §§ 110.1-B-2, 110.1-C. For its determination that Plaintiff's CGM is not a "defined benefit", the Appeals Council relied on the benefit category language of LCA A33614/A52464 (which is referenced as a related coverage document in LCD L15530/ L33822). The Appeals Council examined the evidence in the record and followed the applicable (and well-established) Medicare statutory and regulatory guidance pertaining to what a "benefit category"

is or is not. AR 3-13. It determined that Plaintiff's CGM cannot be used to make a medical decision and was therefore not a "defined benefit" within the meaning of the Medicare statute. *See* pp. 3-4 of this memorandum. As a result, the Appeals Council's decision excluding Plaintiff's CGM as a "defined benefit" that is, a DME, is supported by substantial evidence in the record, and should be affirmed.

## V. CONCLUSION

For the above reasons, the Secretary respectfully requests that the Court affirm the decision of the Appeals Council, deny Plaintiff's Motion for Summary Judgment, and dismiss the Complaint.

Respectfully submitted,

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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the court, which system will serve all counsel electronically, on this second day of March 2017.

*/s/ Anita Johnson*